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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/692,084	08/08/1996	MOSES RODRIGUEZ	1199-1-001-C	3108

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EXAMINER
DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
1645	34

DATE MAILED: 05/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/692,084	Rodriguez et al
Examiner	**Art Unit**
Patricia A. Duffy	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 4, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above, claim(s) *5-8 and 15-18* is/are withdrawn from consideration.

5) ☒ Claim(s) *20 and 21* is/are allowed.

6) ☒ Claim(s) *1-4, 9-14, and 19* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-21* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Amendment

1. The amendment filed 3-4-02 has been entered into the record. Claims 1-4, 9-14, 20 and 21 are under examination. Claims 5-8 and 15-17 have been withdrawn from consideration. Claims 20 and 21 are allowed.

2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

3. This application contains claims 5-8 and 15-17 drawn to an invention nonelected with traverse in Paper No. 7, mailed 6-19-97. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed.

Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,591,629. Although the conflicting claims are not identical, they are not patentably distinct from each other the monoclonal antibody species set forth therein anticipates is the parent molecule of the antigen binding fragment of SCH 79.08 claimed and as such the antigen binding-fragment of the monoclonal antibody SCH 79.08 is an obvious variant. Moreover, the SCH 79.08 monoclonal autoantibody itself anticipates the claim in regard to the now generic

"monoclonal autoantibody capable of inducing remyelination" or monoclonal synthetic autoantibody.

6. Claims 1-4, 9-14, and 19 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of stimulating remyelination or treating a demyelinating disease in a mammal by administering to a mammal an effective amount of monoclonal autoantibodies that induce remyelination of central nervous system axons, the specific monoclonal autoantibodies: A2B5, SCH 79.08 and synthetic monoclonal autoantibodies, monoclonal autoantibodies 01, 04, HNK-1 are not enabled for reasons made of record in Paper No. 9, mailed 10-2-97, Paper No. 15, mailed 3-16-99 and in Paper No. 32, mailed 5-7-01.

Applicants arguments have been carefully considered but are not persuasive. Applicants argue that monoclonal antibody clones 01, 04 and HNK-1 are publicly available. As to HNK-1, Applicants provide evidence Attached as Exhibit I, that as indicated in the prior Exhibit D, ATCC offers the HNK-1 clone for sale as deposited by Abo et al. Exhibit I has apparently become detached from the response. An attempt was made to contact the attorney of record to get a supplemental copy, however no supplemental copy was received.

As to the 01 and 04 clones. Applicants is claiming the use of 01 and 04 clones specifically, not any other clone that binds the same antigen. Applicants Exhibits do not

provide for the public availability or on sale of clone 01 and clone 04 as described by the art of record. Other monoclonal antibody clones cited in the Roche and Chemicon documents do not fulfill the deposit requirement/pubic availability issue with respect to these specific clones. the Roche and Chemicon clones are not structurally identical to those it is noted that Applicants' are specifically claiming monoclonal antibody clones "O1" and "O4". They are not claiming any monoclonal that binds the "O1" or "O4" oligodendrocyte antigens. Applicants' have not provided deposit information for monoclonal antibody clones "O1" or "O4" as are specifically claimed. The monoclonal antibody clones "O1" or "O4" are specific clones produced by others, see for example, Kettenmann et al., Neuroscience Letters, 54(2-3):195-199, March 15, 1985 and Bastmeyer et al., Neuroscience Lett, 101(2):127-32, June 19, 1989. The references in the art provide for specific monoclonal antibody clones entitled "O1" or "O4". Applicants are claiming the use of monoclonal antibodies produced by these specific clones, not by other clones that bind the same antigen as the monoclonal antibodies specifically known to the art at monoclonal antibody clones "O1" or "O4". Applicants argue that the "O1" or "O4" antibodies of Roche that are publicly available were those used by applicants. The clones provided by Roche or Chemicon are not entitled "O1" or "O4" and therefore do not fulfill the public availability requirement, because it is specific clones "O1" and "O4" that are

required, not look-alikes. It is also not persuasive because the specification describes lists the "O1" and "O4" with other *specific monoclonal antibody clones*. Consequently, the only reasonable interpretation of the passage as set forth in the specification is that applicants intended monoclonal antibody clone "O1" or "O4" as described in the art. Applicants' specification does not direct one of skill in the art to either the Roche or Chemicon antibodies, or monoclonal antibodies that bind the "01" or "04" antigens as alleged. The specification directs one to specific monoclonal antibodies "O1" and "O4" of the art and not to the Roche or Chemicon antibodies as asserted (see for example page 9, lines 4-10). Applicants' claims are directed to a specific exact clone. There is no evidence that the monoclonal antibody clones "O1" or "O4" of the prior art were obtained from Roche or Chemicon. Since the claims are to a specific exact clone, it is that clone, not a similar one, producing that exactly identical antibody which is required to be deposited. Applicants' declaration is not persuasive to this point because it does not provide evidence that the publicly available monoclonal antibodies provided by Roche that bind the "O1" or "O4" antigen have the same exact structure as the monoclonal antibody clones "O1" or "O4" of the art that are taught by this specification. That Chemicon International clearly references the original "O1" and "O4" antibodies does not establishes that the original monoclonal antibodies termed "O1" and "04" are structurally identical to those provided by

Chemicon or Roche. As previously set forth, binding of the same antigen, is not the same as claiming a specific monoclonal antibody clone. The record indicates that one skilled in the art would recognize that a fair reading of the passage in the specification indicates that applicants were discussing specific monoclonal antibody clones, not any monoclonal antibody that bound the same antigen. Applicants arguments remain not persuasive.

The new claims as now drawn to isolated to administration of monoclonal autoantibodies or monoclonal autoantibodies that are synthetic and that induce remyelination of central nervous system axons are enabled.

The rejection is maintained.

7. The rejection of claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Abo et al (J. Immunol., 127:1024-1029, 1981) or American Type Culture Collection Catalog, 1992, page 435 is maintained for reasons made of record.

Applicants have amended the claim to generically recite monoclonal autoantibody. The specification teaches monoclonal antibody HNK-1 is an autoantibody. As such the product claim is anticipated. Further since monoclonal antibodies are manufactured (i.e. synthesized), HNK-1 broadly reads on the claim as it recites monoclonal synthetic autoantibodies. Applicants removal of the recitation of HNK-1 does not obviate the rejection as it applies to the now broader recitations as set forth above.

Status of Claims

8. Claims 1-4, 9-14, and 19 stand rejected. Claims 20 and 21 are allowed.

9. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Thursday and Saturday from 10:30 AM to 7:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
May 28, 2002

Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600